NCA of PK profiles after first dose and at steady state

Default Subtitle

**04-Dec-2023**

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Summary statistics for PK parameters by dose group

**Summary statistics for PK parameters by dose group of Plasma C (C) - First dose**

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Profile | Group | Name (Unit) | Na | Mean (SD) | CV% mean | Geo-mean | CV% geo-mean | Median | [Min, Max] |
| First dose | 10mg\_OD\_Oral | AUC %Extrapolation Obs (%) | 9 | 10.22 (5.469) | 53.52 | 8.433 | 85.22 | 10.78 | [2.019, 17.77] |
|  |  | AUC %Extrapolation Pred (%) | 9 | 10.23 (5.501) | 53.8 | 8.444 | 84.7 | 10.7 | [1.992, 17.07] |
|  |  | AUC All (ug/L\*h) | 10 | 1328 (231.7) | 17.45 | 1310 | 17.53 | 1317 | [1054, 1699] |
|  |  | AUC Infinity Obs (ug/L\*h) | 9 | 1523 (303.1) | 19.9 | 1495 | 20.82 | 1585 | [1111, 1997] |
|  |  | AUC Infinity Obs Norm by Dose (ug/L\*h/mg) | 9 | 152.3 (30.31) | 19.9 | 149.5 | 20.82 | 158.5 | [111.1, 199.7] |
|  |  | AUC Infinity Pred (ug/L\*h) | 9 | 1523 (305.6) | 20.06 | 1495 | 20.92 | 1572 | [1114, 2013] |
|  |  | AUC Infinity Pred Norm by Dose (ug/L\*h/mg) | 9 | 152.3 (30.56) | 20.06 | 149.5 | 20.92 | 157.2 | [111.4, 201.3] |
|  |  | AUC Over Dosing Interval (ug/L\*h) | 9 | 1357 (226) | 16.66 | 1340 | 16.94 | 1331 | [1054, 1699] |
|  |  | AUC Over Dosing Interval Norm by Dose (ug/L\*h/mg) | 9 | 135.7 (22.6) | 16.66 | 134 | 16.94 | 133.1 | [105.4, 169.9] |
|  |  | AUC to Last Nonzero Conc (ug/L\*h) | 10 | 1328 (231.7) | 17.45 | 1310 | 17.53 | 1317 | [1054, 1699] |
|  |  | AUC to Last Nonzero Conc Norm by Dose (ug/L\*h/mg) | 10 | 132.8 (23.17) | 17.45 | 131 | 17.53 | 131.7 | [105.4, 169.9] |
|  |  | Average Concentration (ug/L) | 9 | 56.54 (9.418) | 16.66 | 55.84 | 16.94 | 55.45 | [43.94, 70.79] |
|  |  | Conc Trough (ug/L) | 9 | 15.46 (7.327) | 47.39 | 13.37 | 69.57 | 18.63 | [4.48, 24.46] |
|  |  | Half-Life Lambda z (h) | 9 | 6.75 (1.713) | 25.38 | 6.534 | 28.53 | 7.203 | [3.897, 8.54] |
|  |  | Last Nonzero Conc (ug/L) | 10 | 15.98 (7.103) | 44.44 | 13.97 | 66.9 | 18.66 | [4.48, 24.46] |
|  |  | Last Nonzero Conc Pred (ug/L) | 9 | 15.48 (7.454) | 48.15 | 13.39 | 68.96 | 18.53 | [4.42, 25.77] |
|  |  | Max Conc (ug/L) | 10 | 111 (24.21) | 21.8 | 108.3 | 25.07 | 113.2 | [62.33, 138.3] |
|  |  | Max Conc Norm by Dose (ug/L/mg) | 10 | 11.1 (2.421) | 21.8 | 10.83 | 25.07 | 11.32 | [6.233, 13.83] |
|  |  | Min Conc (ug/L) | 10 | 0 (0) | -c | -d | -d | 0 | [0, 0] |
|  |  | Min Conc Norm by Dose (ug/L/mg) | 10 | 0 (0) | -c | -d | -d | 0 | [0, 0] |
|  |  | Number of Points for Lambda z (-) | 10 | 3.9 (0.7379) | 18.92 | 3.837 | 19.34 | 4 | [3, 5] |
|  |  | R Squared Adjusted (-) | 9 | 0.9842 (0.01379) | 1.401 | 0.9842 | 1.411 | 0.9893 | [0.9559, 0.999] |
|  |  | Span (-) | 9 | 2.591 (1.059) | 40.87 | 2.414 | 40.99 | 1.933 | [1.526, 4.182] |
|  |  | Time Until First Nonzero Conc (h) | 10 | 0 (0) | -c | -d | -d | 0 | [0, 0] |
|  |  | Time of CMAX (h) | 10 | 3.2 (1.932) | 60.38 | 2.828 | 52.11 | 2 | [2, 8] |
|  |  | Time of CMIN Observation (h) | 10 | 0 (0) | -c | -d | -d | 0 | [0, 0] |
|  |  | Time of Last Nonzero Conc (h) | 10 | 24 (0) | 0 | 24 | 0 | 24 | [24, 24] |
|  |  | Total CL Obs by F (L/h) | 9 | 6.818 (1.44) | 21.12 | 6.689 | 20.82 | 6.308 | [5.007, 9.004] |
|  |  | Total CL Pred by F (L/h) | 9 | 6.819 (1.444) | 21.18 | 6.688 | 20.92 | 6.361 | [4.967, 8.975] |
|  |  | Vz Obs by F (L) | 9 | 64.05 (11.67) | 18.22 | 63.05 | 19.3 | 62.11 | [45.06, 77.71] |
|  |  | Vz Pred by F (L) | 9 | 64.05 (11.72) | 18.3 | 63.05 | 19.32 | 61.92 | [45.07, 78.38] |

a Number depends on (reliably) calculated parameters.
CV% = coefficient of variation (%)=SD/mean*100.*
*Geo-mean: Geometric mean.*
*CV% geo-mean=(sqrt (exp (variance for log transformed data)-1))*100.
b SD not presented when N=1.
c CV% mean not presented when the mean is 0 or N=1.
d Geo-mean and CV% geo-mean not presented when the minimum value is zero or N=1.
Values in table are reported with 4 significant digits.
IQnca version: 1.3.1.9000
Script: compliance
Output: output/tables/01\_SummaryAll\_NCA.rmd
Execution date: 2023-12-04 14:26:26.494404

**Summary statistics for PK parameters by dose group of Plasma C (C) - Steady-state dose**

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Profile | Group | Name (Unit) | Na | Mean (SD) | CV% mean | Geo-mean | CV% geo-mean | Median | [Min, Max] |
| Steady-state dose | 10mg\_OD\_Oral | AUC %Extrapolation Obs (%) | 9 | 5.922 (2.68) | 45.25 | 5.321 | 55.11 | 6.231 | [2.173, 10.3] |
|  |  | AUC %Extrapolation Pred (%) | 9 | 5.713 (2.558) | 44.78 | 5.162 | 52.98 | 5.768 | [2.197, 10.27] |
|  |  | AUC All (ug/L\*h) | 10 | 2804 (742.7) | 26.49 | 2703 | 30.5 | 2927 | [1526, 3612] |
|  |  | AUC Infinity Obs (ug/L\*h) | 9 | 3060 (758.5) | 24.79 | 2958 | 29.85 | 3311 | [1627, 3854] |
|  |  | AUC Infinity Obs Norm by Dose (ug/L\*h/mg) | 9 | 306 (75.85) | 24.79 | 295.8 | 29.85 | 331.1 | [162.7, 385.4] |
|  |  | AUC Infinity Pred (ug/L\*h) | 9 | 3055 (763.7) | 25 | 2951 | 30.15 | 3308 | [1619, 3853] |
|  |  | AUC Infinity Pred Norm by Dose (ug/L\*h/mg) | 9 | 305.5 (76.37) | 25 | 295.1 | 30.15 | 330.8 | [161.9, 385.3] |
|  |  | AUC Over Dosing Interval (ug/L\*h) | 9 | 1805 (340) | 18.84 | 1774 | 20.07 | 1869 | [1246, 2294] |
|  |  | AUC Over Dosing Interval Norm by Dose (ug/L\*h/mg) | 9 | 180.5 (34) | 18.84 | 177.4 | 20.07 | 186.9 | [124.6, 229.4] |
|  |  | AUC to Last Nonzero Conc (ug/L\*h) | 10 | 2804 (742.7) | 26.49 | 2703 | 30.5 | 2927 | [1526, 3612] |
|  |  | AUC to Last Nonzero Conc Norm by Dose (ug/L\*h/mg) | 10 | 280.4 (74.27) | 26.49 | 270.3 | 30.5 | 292.7 | [152.6, 361.2] |
|  |  | Average Concentration (ug/L) | 9 | 75.2 (14.17) | 18.84 | 73.94 | 20.07 | 77.86 | [51.93, 95.58] |
|  |  | Conc Trough (ug/L) | 9 | 29.05 (8.098) | 27.88 | 27.7 | 36.69 | 31.95 | [12.19, 37.1] |
|  |  | Half-Life Lambda z (h) | 9 | 44.16 (16.43) | 37.2 | 41.33 | 41.35 | 44.83 | [22.04, 74.6] |
|  |  | Last Nonzero Conc (ug/L) | 10 | 2.733 (1.181) | 43.2 | 2.537 | 41.45 | 2.664 | [1.556, 5.462] |
|  |  | Last Nonzero Conc Pred (ug/L) | 9 | 2.715 (1.018) | 37.51 | 2.555 | 38.19 | 2.743 | [1.574, 4.768] |
|  |  | Max Conc (ug/L) | 10 | 133.7 (24.57) | 18.38 | 131.6 | 18.83 | 131.4 | [92.84, 179.5] |
|  |  | Max Conc Norm by Dose (ug/L/mg) | 10 | 13.37 (2.457) | 18.38 | 13.16 | 18.83 | 13.14 | [9.284, 17.95] |
|  |  | Min Conc (ug/L) | 10 | 25.98 (10.55) | 40.6 | 23.56 | 53.19 | 31.58 | [9.415, 37.1] |
|  |  | Min Conc Norm by Dose (ug/L/mg) | 10 | 2.598 (1.055) | 40.6 | 2.356 | 53.19 | 3.158 | [0.9415, 3.71] |
|  |  | Number of Points for Lambda z (-) | 10 | 3.2 (0.4216) | 13.18 | 3.178 | 12.17 | 3 | [3, 4] |
|  |  | R Squared Adjusted (-) | 9 | 0.9712 (0.03445) | 3.547 | 0.9707 | 3.59 | 0.9866 | [0.9217, 0.9997] |
|  |  | Span (-) | 9 | 2.461 (0.526) | 21.38 | 2.41 | 22.2 | 2.453 | [1.609, 3.359] |
|  |  | Time Until First Nonzero Conc (h) | 10 | 0 (0) | -c | -d | -d | 0 | [0, 0] |
|  |  | Time of CMAX (h) | 10 | 3.6 (0.8433) | 23.42 | 3.482 | 29.86 | 4 | [2, 4] |
|  |  | Time of CMIN Observation (h) | 10 | 14.4 (12.39) | 86.07 | -d | -d | 24 | [0, 24] |
|  |  | Time of Last Nonzero Conc (h) | 10 | 148.8 (40.48) | 27.2 | 141.8 | 36.9 | 168 | [72, 168] |
|  |  | Total CL by F for Dose Int (L/h) | 10 | 5.877 (1.213) | 20.63 | 5.769 | 20.36 | 5.425 | [4.359, 8.024] |
|  |  | Vz for Dose Int at SS by F (L) | 9 | 353.1 (120.3) | 34.07 | 336 | 34.17 | 355.6 | [224.7, 560.9] |

a Number depends on (reliably) calculated parameters.
CV% = coefficient of variation (%)=SD/mean*100.*
*Geo-mean: Geometric mean.*
*CV% geo-mean=(sqrt (exp (variance for log transformed data)-1))*100.
b SD not presented when N=1.
c CV% mean not presented when the mean is 0 or N=1.
d Geo-mean and CV% geo-mean not presented when the minimum value is zero or N=1.
Values in table are reported with 4 significant digits.
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Script: compliance
Output: output/tables/01\_SummaryAll\_NCA.rmd
Execution date: 2023-12-04 14:26:26.537803

Summary statistics for PK parameters by dose group

**Summary statistics for PK parameters by dose group of Plasma C (C) - First dose**

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Profile | Group | Name (Unit) | Na | Mean (SD) | CV% mean | Geo-mean | CV% geo-mean | Median | [Min, Max] |
| First dose | 10mg\_OD\_Oral | AUC Over Dosing Interval (ug/L\*h) | 9 | 1357 (226) | 16.66 | 1340 | 16.94 | 1331 | [1054, 1699] |
|  |  | Lambda z (1/h) | 9 | 0.11 (0.03342) | 30.37 | 0.1061 | 28.53 | 0.09623 | [0.08117, 0.1779] |
|  |  | Max Conc (ug/L) | 10 | 111 (24.21) | 21.8 | 108.3 | 25.07 | 113.2 | [62.33, 138.3] |
|  |  | R Squared Adjusted (-) | 9 | 0.9842 (0.01379) | 1.401 | 0.9842 | 1.411 | 0.9893 | [0.9559, 0.999] |
|  |  | Time of CMAX (h) | 10 | 3.2 (1.932) | 60.38 | 2.828 | 52.11 | 2 | [2, 8] |

a Number depends on (reliably) calculated parameters.
CV% = coefficient of variation (%)=SD/mean*100.*
*Geo-mean: Geometric mean.*
*CV% geo-mean=(sqrt (exp (variance for log transformed data)-1))*100.
b SD not presented when N=1.
c CV% mean not presented when the mean is 0 or N=1.
d Geo-mean and CV% geo-mean not presented when the minimum value is zero or N=1.
Values in table are reported with 4 significant digits.
IQnca version: 1.3.1.9000
Script: compliance
Output: output/tables/02\_SummaryKey\_NCA.rmd
Execution date: 2023-12-04 14:26:26.635825

**Summary statistics for PK parameters by dose group of Plasma C (C) - Steady-state dose**

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Profile | Group | Name (Unit) | Na | Mean (SD) | CV% mean | Geo-mean | CV% geo-mean | Median | [Min, Max] |
| Steady-state dose | 10mg\_OD\_Oral | AUC Over Dosing Interval (ug/L\*h) | 9 | 1805 (340) | 18.84 | 1774 | 20.07 | 1869 | [1246, 2294] |
|  |  | Lambda z (1/h) | 9 | 0.01803 (0.007608) | 42.19 | 0.01677 | 41.35 | 0.01546 | [0.009292, 0.03146] |
|  |  | Max Conc (ug/L) | 10 | 133.7 (24.57) | 18.38 | 131.6 | 18.83 | 131.4 | [92.84, 179.5] |
|  |  | R Squared Adjusted (-) | 9 | 0.9712 (0.03445) | 3.547 | 0.9707 | 3.59 | 0.9866 | [0.9217, 0.9997] |
|  |  | Time of CMAX (h) | 10 | 3.6 (0.8433) | 23.42 | 3.482 | 29.86 | 4 | [2, 4] |

a Number depends on (reliably) calculated parameters.
CV% = coefficient of variation (%)=SD/mean*100.*
*Geo-mean: Geometric mean.*
*CV% geo-mean=(sqrt (exp (variance for log transformed data)-1))*100.
b SD not presented when N=1.
c CV% mean not presented when the mean is 0 or N=1.
d Geo-mean and CV% geo-mean not presented when the minimum value is zero or N=1.
Values in table are reported with 4 significant digits.
IQnca version: 1.3.1.9000
Script: compliance
Output: output/tables/02\_SummaryKey\_NCA.rmd
Execution date: 2023-12-04 14:26:26.645533

Individual pharmacokinetic parameters

**Individual pharmacokinetic parameters of Plasma C (C)**

* USUBJID: 1

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Profile | Group | Dose [mg] | Description | Parameter (Unit) | Value |
| First dose | 10mg\_OD\_Oral | 10 | Number of Points for Lambda z | LAMZNPT (-) | 4 |
|  |  |  | R Squared Adjusted | R2ADJ (-) | 0.999021 |
|  |  |  | Half-Life Lambda z | LAMZHL (h) | 3.89714 |
|  |  |  | Span | SPAN (-) | 4.10558 |
|  |  |  | Time Until First Nonzero Conc | TLAG (h) | 0 |
|  |  |  | Time of CMAX | TMAX (h) | 2 |
|  |  |  | Max Conc | CMAX (ug/L) | 134.221 |
|  |  |  | Max Conc Norm by Dose | CMAXD (ug/L/mg) | 13.4221 |
|  |  |  | Time of CMIN Observation | TMIN (h) | 0 |
|  |  |  | Min Conc | CMIN (ug/L) | 0 |
|  |  |  | Min Conc Norm by Dose | CMIND (ug/L/mg) | 0 |
|  |  |  | Time of Last Nonzero Conc | TLST (h) | 24 |
|  |  |  | Last Nonzero Conc | CLST (ug/L) | 4.4798 |
|  |  |  | Last Nonzero Conc Pred | CLSTP (ug/L) | 4.41988 |
|  |  |  | Average Concentration | CAVG (ug/L) | 50.9401 |
|  |  |  | Conc Trough | CTAU (ug/L) | 4.4798 |
|  |  |  | AUC All | AUCALL (ug/L\*h) | 1222.56 |
|  |  |  | AUC Infinity Obs | AUCIFO (ug/L\*h) | 1247.75 |
|  |  |  | AUC Infinity Obs Norm by Dose | AUCIFOD (ug/L\*h/mg) | 124.775 |
|  |  |  | AUC Infinity Pred | AUCIFP (ug/L\*h) | 1247.41 |
|  |  |  | AUC Infinity Pred Norm by Dose | AUCIFPD (ug/L\*h/mg) | 124.741 |
|  |  |  | AUC to Last Nonzero Conc | AUCLST (ug/L\*h) | 1222.56 |
|  |  |  | AUC to Last Nonzero Conc Norm by Dose | AUCLSTD (ug/L\*h/mg) | 122.256 |
|  |  |  | AUC %Extrapolation Obs | AUCPEO (%) | 2.0186 |
|  |  |  | AUC %Extrapolation Pred | AUCPEP (%) | 1.99214 |
|  |  |  | AUC Over Dosing Interval | AUCTAU (ug/L\*h) | 1222.56 |
|  |  |  | AUC Over Dosing Interval Norm by Dose | AUCTAUD (ug/L\*h/mg) | 122.256 |
|  |  |  | Total CL Obs by F | CLFO (L/h) | 8.01443 |
|  |  |  | Total CL Pred by F | CLFP (L/h) | 8.01659 |
|  |  |  | Vz Obs by F | VZFO (L) | 45.0601 |
|  |  |  | Vz Pred by F | VZFP (L) | 45.0723 |

NC: Not calculated.
Number of significant digits: 6
IQnca version: 1.3.1.9000
Script: compliance
Output: output/listings/01\_listings\_NCA.rmd
Execution date: 2023-12-04 14:26:26.173698

**Individual pharmacokinetic parameters of Plasma C (C)**

* USUBJID: 1

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Profile | Group | Dose [mg] | Description | Parameter (Unit) | Value |
| Steady-state dose | 10mg\_OD\_Oral | 10 | Number of Points for Lambda z | LAMZNPT (-) | 4 |
|  |  |  | R Squared Adjusted | R2ADJ (-) | 0.802418 c |
|  |  |  | Half-Life Lambda z | LAMZHL (h) | 55.8901 c |
|  |  |  | Span | SPAN (-) | 2.57648 c |
|  |  |  | Time Until First Nonzero Conc | TLAG (h) | 0 |
|  |  |  | Time of CMAX | TMAX (h) | 4 |
|  |  |  | Max Conc | CMAX (ug/L) | 141.293 |
|  |  |  | Max Conc Norm by Dose | CMAXD (ug/L/mg) | 14.1293 |
|  |  |  | Time of CMIN Observation | TMIN (h) | 0 |
|  |  |  | Min Conc | CMIN (ug/L) | 12.6546 |
|  |  |  | Min Conc Norm by Dose | CMIND (ug/L/mg) | 1.26546 |
|  |  |  | Time of Last Nonzero Conc | TLST (h) | 168 |
|  |  |  | Last Nonzero Conc | CLST (ug/L) | 1.7742 |
|  |  |  | Last Nonzero Conc Pred | CLSTP (ug/L) | 1.71416 c |
|  |  |  | Average Concentration | CAVG (ug/L) | 58.4916 c |
|  |  |  | Conc Trough | CTAU (ug/L) | 13.5794 c |
|  |  |  | AUC All | AUCALL (ug/L\*h) | 2086.1 |
|  |  |  | AUC Infinity Obs | AUCIFO (ug/L\*h) | 2229.15 c |
|  |  |  | AUC Infinity Obs Norm by Dose | AUCIFOD (ug/L\*h/mg) | 222.915 c |
|  |  |  | AUC Infinity Pred | AUCIFP (ug/L\*h) | 2224.31 c |
|  |  |  | AUC Infinity Pred Norm by Dose | AUCIFPD (ug/L\*h/mg) | 222.431 c |
|  |  |  | AUC to Last Nonzero Conc | AUCLST (ug/L\*h) | 2086.1 |
|  |  |  | AUC to Last Nonzero Conc Norm by Dose | AUCLSTD (ug/L\*h/mg) | 208.61 |
|  |  |  | AUC %Extrapolation Obs | AUCPEO (%) | 6.41759 c |
|  |  |  | AUC %Extrapolation Pred | AUCPEP (%) | 6.21393 c |
|  |  |  | AUC Over Dosing Interval | AUCTAU (ug/L\*h) | 1403.8 c |
|  |  |  | AUC Over Dosing Interval Norm by Dose | AUCTAUD (ug/L\*h/mg) | 140.38 c |
|  |  |  | Total CL by F for Dose Int | CLFSS (L/h) | 7.12353 |
|  |  |  | Vz for Dose Int at SS by F | VZFSS (L) | 574.387 c |

NC: Not calculated.
Number of significant digits: 6
c Value not reliably calculated. Reason: R2ADJ<0.85. Value was not considered for summary and inferential procedures.
IQnca version: 1.3.1.9000
Script: compliance
Output: output/listings/01\_listings\_NCA.rmd
Execution date: 2023-12-04 14:26:26.18535

**Individual pharmacokinetic parameters of Plasma C (C)**

* USUBJID: 10

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Profile | Group | Dose [mg] | Description | Parameter (Unit) | Value |
| First dose | 10mg\_OD\_Oral | 10 | Number of Points for Lambda z | LAMZNPT (-) | 3 |
|  |  |  | R Squared Adjusted | R2ADJ (-) | 0.994917 a |
|  |  |  | Half-Life Lambda z | LAMZHL (h) | 8.67853 a |
|  |  |  | Span | SPAN (-) | 1.38272 a |
|  |  |  | Time Until First Nonzero Conc | TLAG (h) | 0 |
|  |  |  | Time of CMAX | TMAX (h) | 8 |
|  |  |  | Max Conc | CMAX (ug/L) | 62.3266 |
|  |  |  | Max Conc Norm by Dose | CMAXD (ug/L/mg) | 6.23266 |
|  |  |  | Time of CMIN Observation | TMIN (h) | 0 |
|  |  |  | Min Conc | CMIN (ug/L) | 0 |
|  |  |  | Min Conc Norm by Dose | CMIND (ug/L/mg) | 0 |
|  |  |  | Time of Last Nonzero Conc | TLST (h) | 24 |
|  |  |  | Last Nonzero Conc | CLST (ug/L) | 20.6831 |
|  |  |  | Last Nonzero Conc Pred | CLSTP (ug/L) | 20.8766 a |
|  |  |  | Average Concentration | CAVG (ug/L) | 44.5427 a |
|  |  |  | Conc Trough | CTAU (ug/L) | 20.6831 a |
|  |  |  | AUC All | AUCALL (ug/L\*h) | 1069.02 |
|  |  |  | AUC Infinity Obs | AUCIFO (ug/L\*h) | 1327.99 a |
|  |  |  | AUC Infinity Obs Norm by Dose | AUCIFOD (ug/L\*h/mg) | 132.799 a |
|  |  |  | AUC Infinity Pred | AUCIFP (ug/L\*h) | 1330.41 a |
|  |  |  | AUC Infinity Pred Norm by Dose | AUCIFPD (ug/L\*h/mg) | 133.041 a |
|  |  |  | AUC to Last Nonzero Conc | AUCLST (ug/L\*h) | 1069.02 |
|  |  |  | AUC to Last Nonzero Conc Norm by Dose | AUCLSTD (ug/L\*h/mg) | 106.902 |
|  |  |  | AUC %Extrapolation Obs | AUCPEO (%) | 19.5004 a |
|  |  |  | AUC %Extrapolation Pred | AUCPEP (%) | 19.6469 a |
|  |  |  | AUC Over Dosing Interval | AUCTAU (ug/L\*h) | 1069.02 a |
|  |  |  | AUC Over Dosing Interval Norm by Dose | AUCTAUD (ug/L\*h/mg) | 106.902 a |
|  |  |  | Total CL Obs by F | CLFO (L/h) | 7.53019 a |
|  |  |  | Total CL Pred by F | CLFP (L/h) | 7.51648 a |
|  |  |  | Vz Obs by F | VZFO (L) | 94.2816 a |
|  |  |  | Vz Pred by F | VZFP (L) | 94.11 a |

NC: Not calculated.
Number of significant digits: 6
a Value not reliably calculated. Reason: SPAN<1.5. Value was not considered for summary and inferential procedures.
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Execution date: 2023-12-04 14:26:26.194694

**Individual pharmacokinetic parameters of Plasma C (C)**

* USUBJID: 10

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Profile | Group | Dose [mg] | Description | Parameter (Unit) | Value |
| Steady-state dose | 10mg\_OD\_Oral | 10 | Number of Points for Lambda z | LAMZNPT (-) | 3 |
|  |  |  | R Squared Adjusted | R2ADJ (-) | 0.92175 |
|  |  |  | Half-Life Lambda z | LAMZHL (h) | 56.4676 |
|  |  |  | Span | SPAN (-) | 2.12511 |
|  |  |  | Time Until First Nonzero Conc | TLAG (h) | 0 |
|  |  |  | Time of CMAX | TMAX (h) | 4 |
|  |  |  | Max Conc | CMAX (ug/L) | 92.845 |
|  |  |  | Max Conc Norm by Dose | CMAXD (ug/L/mg) | 9.2845 |
|  |  |  | Time of CMIN Observation | TMIN (h) | 24 |
|  |  |  | Min Conc | CMIN (ug/L) | 31.9476 |
|  |  |  | Min Conc Norm by Dose | CMIND (ug/L/mg) | 3.19476 |
|  |  |  | Time of Last Nonzero Conc | TLST (h) | 168 |
|  |  |  | Last Nonzero Conc | CLST (ug/L) | 2.8886 |
|  |  |  | Last Nonzero Conc Pred | CLSTP (ug/L) | 2.79114 |
|  |  |  | Average Concentration | CAVG (ug/L) | 66.4187 |
|  |  |  | Conc Trough | CTAU (ug/L) | 31.9476 |
|  |  |  | AUC All | AUCALL (ug/L\*h) | 2836.24 |
|  |  |  | AUC Infinity Obs | AUCIFO (ug/L\*h) | 3071.56 |
|  |  |  | AUC Infinity Obs Norm by Dose | AUCIFOD (ug/L\*h/mg) | 307.156 |
|  |  |  | AUC Infinity Pred | AUCIFP (ug/L\*h) | 3063.62 |
|  |  |  | AUC Infinity Pred Norm by Dose | AUCIFPD (ug/L\*h/mg) | 306.362 |
|  |  |  | AUC to Last Nonzero Conc | AUCLST (ug/L\*h) | 2836.24 |
|  |  |  | AUC to Last Nonzero Conc Norm by Dose | AUCLSTD (ug/L\*h/mg) | 283.624 |
|  |  |  | AUC %Extrapolation Obs | AUCPEO (%) | 7.66129 |
|  |  |  | AUC %Extrapolation Pred | AUCPEP (%) | 7.42199 |
|  |  |  | AUC Over Dosing Interval | AUCTAU (ug/L\*h) | 1594.05 |
|  |  |  | AUC Over Dosing Interval Norm by Dose | AUCTAUD (ug/L\*h/mg) | 159.405 |
|  |  |  | Total CL by F for Dose Int | CLFSS (L/h) | 6.27333 |
|  |  |  | Vz for Dose Int at SS by F | VZFSS (L) | 511.06 |

NC: Not calculated.
Number of significant digits: 6
IQnca version: 1.3.1.9000
Script: compliance
Output: output/listings/01\_listings\_NCA.rmd
Execution date: 2023-12-04 14:26:26.204206

**Individual pharmacokinetic parameters of Plasma C (C)**

* USUBJID: 2

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Profile | Group | Dose [mg] | Description | Parameter (Unit) | Value |
| First dose | 10mg\_OD\_Oral | 10 | Number of Points for Lambda z | LAMZNPT (-) | 3 |
|  |  |  | R Squared Adjusted | R2ADJ (-) | 0.989339 |
|  |  |  | Half-Life Lambda z | LAMZHL (h) | 7.86543 |
|  |  |  | Span | SPAN (-) | 1.52566 |
|  |  |  | Time Until First Nonzero Conc | TLAG (h) | 0 |
|  |  |  | Time of CMAX | TMAX (h) | 2 |
|  |  |  | Max Conc | CMAX (ug/L) | 106.292 |
|  |  |  | Max Conc Norm by Dose | CMAXD (ug/L/mg) | 10.6292 |
|  |  |  | Time of CMIN Observation | TMIN (h) | 0 |
|  |  |  | Min Conc | CMIN (ug/L) | 0 |
|  |  |  | Min Conc Norm by Dose | CMIND (ug/L/mg) | 0 |
|  |  |  | Time of Last Nonzero Conc | TLST (h) | 24 |
|  |  |  | Last Nonzero Conc | CLST (ug/L) | 18.6343 |
|  |  |  | Last Nonzero Conc Pred | CLSTP (ug/L) | 18.914 |
|  |  |  | Average Concentration | CAVG (ug/L) | 57.4196 |
|  |  |  | Conc Trough | CTAU (ug/L) | 18.6343 |
|  |  |  | AUC All | AUCALL (ug/L\*h) | 1378.07 |
|  |  |  | AUC Infinity Obs | AUCIFO (ug/L\*h) | 1589.52 |
|  |  |  | AUC Infinity Obs Norm by Dose | AUCIFOD (ug/L\*h/mg) | 158.952 |
|  |  |  | AUC Infinity Pred | AUCIFP (ug/L\*h) | 1592.7 |
|  |  |  | AUC Infinity Pred Norm by Dose | AUCIFPD (ug/L\*h/mg) | 159.27 |
|  |  |  | AUC to Last Nonzero Conc | AUCLST (ug/L\*h) | 1378.07 |
|  |  |  | AUC to Last Nonzero Conc Norm by Dose | AUCLSTD (ug/L\*h/mg) | 137.807 |
|  |  |  | AUC %Extrapolation Obs | AUCPEO (%) | 13.3028 |
|  |  |  | AUC %Extrapolation Pred | AUCPEP (%) | 13.4756 |
|  |  |  | AUC Over Dosing Interval | AUCTAU (ug/L\*h) | 1378.07 |
|  |  |  | AUC Over Dosing Interval Norm by Dose | AUCTAUD (ug/L\*h/mg) | 137.807 |
|  |  |  | Total CL Obs by F | CLFO (L/h) | 6.2912 |
|  |  |  | Total CL Pred by F | CLFP (L/h) | 6.27866 |
|  |  |  | Vz Obs by F | VZFO (L) | 71.3889 |
|  |  |  | Vz Pred by F | VZFP (L) | 71.2466 |

NC: Not calculated.
Number of significant digits: 6
IQnca version: 1.3.1.9000
Script: compliance
Output: output/listings/01\_listings\_NCA.rmd
Execution date: 2023-12-04 14:26:26.213594

**Individual pharmacokinetic parameters of Plasma C (C)**

* USUBJID: 2

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Profile | Group | Dose [mg] | Description | Parameter (Unit) | Value |
| Steady-state dose | 10mg\_OD\_Oral | 10 | Number of Points for Lambda z | LAMZNPT (-) | 3 |
|  |  |  | R Squared Adjusted | R2ADJ (-) | 0.99615 |
|  |  |  | Half-Life Lambda z | LAMZHL (h) | 44.8292 |
|  |  |  | Span | SPAN (-) | 2.67683 |
|  |  |  | Time Until First Nonzero Conc | TLAG (h) | 0 |
|  |  |  | Time of CMAX | TMAX (h) | 4 |
|  |  |  | Max Conc | CMAX (ug/L) | 136.231 |
|  |  |  | Max Conc Norm by Dose | CMAXD (ug/L/mg) | 13.6231 |
|  |  |  | Time of CMIN Observation | TMIN (h) | 24 |
|  |  |  | Min Conc | CMIN (ug/L) | 31.2151 |
|  |  |  | Min Conc Norm by Dose | CMIND (ug/L/mg) | 3.12151 |
|  |  |  | Time of Last Nonzero Conc | TLST (h) | 168 |
|  |  |  | Last Nonzero Conc | CLST (ug/L) | 1.6009 |
|  |  |  | Last Nonzero Conc Pred | CLSTP (ug/L) | 1.58591 |
|  |  |  | Average Concentration | CAVG (ug/L) | 75.7867 |
|  |  |  | Conc Trough | CTAU (ug/L) | 31.2151 |
|  |  |  | AUC All | AUCALL (ug/L\*h) | 2819.87 |
|  |  |  | AUC Infinity Obs | AUCIFO (ug/L\*h) | 2923.41 |
|  |  |  | AUC Infinity Obs Norm by Dose | AUCIFOD (ug/L\*h/mg) | 292.341 |
|  |  |  | AUC Infinity Pred | AUCIFP (ug/L\*h) | 2922.44 |
|  |  |  | AUC Infinity Pred Norm by Dose | AUCIFPD (ug/L\*h/mg) | 292.244 |
|  |  |  | AUC to Last Nonzero Conc | AUCLST (ug/L\*h) | 2819.87 |
|  |  |  | AUC to Last Nonzero Conc Norm by Dose | AUCLSTD (ug/L\*h/mg) | 281.987 |
|  |  |  | AUC %Extrapolation Obs | AUCPEO (%) | 3.54168 |
|  |  |  | AUC %Extrapolation Pred | AUCPEP (%) | 3.50968 |
|  |  |  | AUC Over Dosing Interval | AUCTAU (ug/L\*h) | 1818.88 |
|  |  |  | AUC Over Dosing Interval Norm by Dose | AUCTAUD (ug/L\*h/mg) | 181.888 |
|  |  |  | Total CL by F for Dose Int | CLFSS (L/h) | 5.49789 |
|  |  |  | Vz for Dose Int at SS by F | VZFSS (L) | 355.575 |

NC: Not calculated.
Number of significant digits: 6
IQnca version: 1.3.1.9000
Script: compliance
Output: output/listings/01\_listings\_NCA.rmd
Execution date: 2023-12-04 14:26:26.222796

**Individual pharmacokinetic parameters of Plasma C (C)**

* USUBJID: 3

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Profile | Group | Dose [mg] | Description | Parameter (Unit) | Value |
| First dose | 10mg\_OD\_Oral | 10 | Number of Points for Lambda z | LAMZNPT (-) | 4 |
|  |  |  | R Squared Adjusted | R2ADJ (-) | 0.955882 |
|  |  |  | Half-Life Lambda z | LAMZHL (h) | 8.45713 |
|  |  |  | Span | SPAN (-) | 1.8919 |
|  |  |  | Time Until First Nonzero Conc | TLAG (h) | 0 |
|  |  |  | Time of CMAX | TMAX (h) | 4 |
|  |  |  | Max Conc | CMAX (ug/L) | 133.266 |
|  |  |  | Max Conc Norm by Dose | CMAXD (ug/L/mg) | 13.3266 |
|  |  |  | Time of CMIN Observation | TMIN (h) | 0 |
|  |  |  | Min Conc | CMIN (ug/L) | 0 |
|  |  |  | Min Conc Norm by Dose | CMIND (ug/L/mg) | 0 |
|  |  |  | Time of Last Nonzero Conc | TLST (h) | 24 |
|  |  |  | Last Nonzero Conc | CLST (ug/L) | 24.4574 |
|  |  |  | Last Nonzero Conc Pred | CLSTP (ug/L) | 25.7707 |
|  |  |  | Average Concentration | CAVG (ug/L) | 70.7883 |
|  |  |  | Conc Trough | CTAU (ug/L) | 24.4574 |
|  |  |  | AUC All | AUCALL (ug/L\*h) | 1698.92 |
|  |  |  | AUC Infinity Obs | AUCIFO (ug/L\*h) | 1997.33 |
|  |  |  | AUC Infinity Obs Norm by Dose | AUCIFOD (ug/L\*h/mg) | 199.733 |
|  |  |  | AUC Infinity Pred | AUCIFP (ug/L\*h) | 2013.35 |
|  |  |  | AUC Infinity Pred Norm by Dose | AUCIFPD (ug/L\*h/mg) | 201.335 |
|  |  |  | AUC to Last Nonzero Conc | AUCLST (ug/L\*h) | 1698.92 |
|  |  |  | AUC to Last Nonzero Conc Norm by Dose | AUCLSTD (ug/L\*h/mg) | 169.892 |
|  |  |  | AUC %Extrapolation Obs | AUCPEO (%) | 14.9403 |
|  |  |  | AUC %Extrapolation Pred | AUCPEP (%) | 15.6172 |
|  |  |  | AUC Over Dosing Interval | AUCTAU (ug/L\*h) | 1698.92 |
|  |  |  | AUC Over Dosing Interval Norm by Dose | AUCTAUD (ug/L\*h/mg) | 169.892 |
|  |  |  | Total CL Obs by F | CLFO (L/h) | 5.0067 |
|  |  |  | Total CL Pred by F | CLFP (L/h) | 4.96685 |
|  |  |  | Vz Obs by F | VZFO (L) | 61.087 |
|  |  |  | Vz Pred by F | VZFP (L) | 60.6008 |

NC: Not calculated.
Number of significant digits: 6
IQnca version: 1.3.1.9000
Script: compliance
Output: output/listings/01\_listings\_NCA.rmd
Execution date: 2023-12-04 14:26:26.232396

**Individual pharmacokinetic parameters of Plasma C (C)**

* USUBJID: 3

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Profile | Group | Dose [mg] | Description | Parameter (Unit) | Value |
| Steady-state dose | 10mg\_OD\_Oral | 10 | Number of Points for Lambda z | LAMZNPT (-) | 3 |
|  |  |  | R Squared Adjusted | R2ADJ (-) | 0.985256 |
|  |  |  | Half-Life Lambda z | LAMZHL (h) | 39.7089 |
|  |  |  | Span | SPAN (-) | 3.02199 |
|  |  |  | Time Until First Nonzero Conc | TLAG (h) | 0 |
|  |  |  | Time of CMAX | TMAX (h) | 4 |
|  |  |  | Max Conc | CMAX (ug/L) | 149.678 |
|  |  |  | Max Conc Norm by Dose | CMAXD (ug/L/mg) | 14.9678 |
|  |  |  | Time of CMIN Observation | TMIN (h) | 24 |
|  |  |  | Min Conc | CMIN (ug/L) | 36.6092 |
|  |  |  | Min Conc Norm by Dose | CMIND (ug/L/mg) | 3.66092 |
|  |  |  | Time of Last Nonzero Conc | TLST (h) | 168 |
|  |  |  | Last Nonzero Conc | CLST (ug/L) | 1.9635 |
|  |  |  | Last Nonzero Conc Pred | CLSTP (ug/L) | 1.923 |
|  |  |  | Average Concentration | CAVG (ug/L) | 89.903 |
|  |  |  | Conc Trough | CTAU (ug/L) | 36.6092 |
|  |  |  | AUC All | AUCALL (ug/L\*h) | 3527.92 |
|  |  |  | AUC Infinity Obs | AUCIFO (ug/L\*h) | 3640.4 |
|  |  |  | AUC Infinity Obs Norm by Dose | AUCIFOD (ug/L\*h/mg) | 364.04 |
|  |  |  | AUC Infinity Pred | AUCIFP (ug/L\*h) | 3638.08 |
|  |  |  | AUC Infinity Pred Norm by Dose | AUCIFPD (ug/L\*h/mg) | 363.808 |
|  |  |  | AUC to Last Nonzero Conc | AUCLST (ug/L\*h) | 3527.92 |
|  |  |  | AUC to Last Nonzero Conc Norm by Dose | AUCLSTD (ug/L\*h/mg) | 352.792 |
|  |  |  | AUC %Extrapolation Obs | AUCPEO (%) | 3.0899 |
|  |  |  | AUC %Extrapolation Pred | AUCPEP (%) | 3.02809 |
|  |  |  | AUC Over Dosing Interval | AUCTAU (ug/L\*h) | 2157.67 |
|  |  |  | AUC Over Dosing Interval Norm by Dose | AUCTAUD (ug/L\*h/mg) | 215.767 |
|  |  |  | Total CL by F for Dose Int | CLFSS (L/h) | 4.63463 |
|  |  |  | Vz for Dose Int at SS by F | VZFSS (L) | 265.508 |

NC: Not calculated.
Number of significant digits: 6
IQnca version: 1.3.1.9000
Script: compliance
Output: output/listings/01\_listings\_NCA.rmd
Execution date: 2023-12-04 14:26:26.242205

**Individual pharmacokinetic parameters of Plasma C (C)**

* USUBJID: 4

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Profile | Group | Dose [mg] | Description | Parameter (Unit) | Value |
| First dose | 10mg\_OD\_Oral | 10 | Number of Points for Lambda z | LAMZNPT (-) | 5 |
|  |  |  | R Squared Adjusted | R2ADJ (-) | 0.990873 |
|  |  |  | Half-Life Lambda z | LAMZHL (h) | 4.78194 |
|  |  |  | Span | SPAN (-) | 4.1824 |
|  |  |  | Time Until First Nonzero Conc | TLAG (h) | 0 |
|  |  |  | Time of CMAX | TMAX (h) | 2 |
|  |  |  | Max Conc | CMAX (ug/L) | 118.596 |
|  |  |  | Max Conc Norm by Dose | CMAXD (ug/L/mg) | 11.8596 |
|  |  |  | Time of CMIN Observation | TMIN (h) | 0 |
|  |  |  | Min Conc | CMIN (ug/L) | 0 |
|  |  |  | Min Conc Norm by Dose | CMIND (ug/L/mg) | 0 |
|  |  |  | Time of Last Nonzero Conc | TLST (h) | 24 |
|  |  |  | Last Nonzero Conc | CLST (ug/L) | 5.5074 |
|  |  |  | Last Nonzero Conc Pred | CLSTP (ug/L) | 6.01936 |
|  |  |  | Average Concentration | CAVG (ug/L) | 44.6951 |
|  |  |  | Conc Trough | CTAU (ug/L) | 5.5074 |
|  |  |  | AUC All | AUCALL (ug/L\*h) | 1072.68 |
|  |  |  | AUC Infinity Obs | AUCIFO (ug/L\*h) | 1110.68 |
|  |  |  | AUC Infinity Obs Norm by Dose | AUCIFOD (ug/L\*h/mg) | 111.068 |
|  |  |  | AUC Infinity Pred | AUCIFP (ug/L\*h) | 1114.21 |
|  |  |  | AUC Infinity Pred Norm by Dose | AUCIFPD (ug/L\*h/mg) | 111.421 |
|  |  |  | AUC to Last Nonzero Conc | AUCLST (ug/L\*h) | 1072.68 |
|  |  |  | AUC to Last Nonzero Conc Norm by Dose | AUCLSTD (ug/L\*h/mg) | 107.268 |
|  |  |  | AUC %Extrapolation Obs | AUCPEO (%) | 3.42088 |
|  |  |  | AUC %Extrapolation Pred | AUCPEP (%) | 3.72703 |
|  |  |  | AUC Over Dosing Interval | AUCTAU (ug/L\*h) | 1072.68 |
|  |  |  | AUC Over Dosing Interval Norm by Dose | AUCTAUD (ug/L\*h/mg) | 107.268 |
|  |  |  | Total CL Obs by F | CLFO (L/h) | 9.00352 |
|  |  |  | Total CL Pred by F | CLFP (L/h) | 8.97498 |
|  |  |  | Vz Obs by F | VZFO (L) | 62.1142 |
|  |  |  | Vz Pred by F | VZFP (L) | 61.9173 |

NC: Not calculated.
Number of significant digits: 6
IQnca version: 1.3.1.9000
Script: compliance
Output: output/listings/01\_listings\_NCA.rmd
Execution date: 2023-12-04 14:26:26.259373

**Individual pharmacokinetic parameters of Plasma C (C)**

* USUBJID: 4

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Profile | Group | Dose [mg] | Description | Parameter (Unit) | Value |
| Steady-state dose | 10mg\_OD\_Oral | 10 | Number of Points for Lambda z | LAMZNPT (-) | 3 |
|  |  |  | R Squared Adjusted | R2ADJ (-) | 0.92182 |
|  |  |  | Half-Life Lambda z | LAMZHL (h) | 23.602 |
|  |  |  | Span | SPAN (-) | 2.03373 |
|  |  |  | Time Until First Nonzero Conc | TLAG (h) | 0 |
|  |  |  | Time of CMAX | TMAX (h) | 4 |
|  |  |  | Max Conc | CMAX (ug/L) | 123.891 |
|  |  |  | Max Conc Norm by Dose | CMAXD (ug/L/mg) | 12.3891 |
|  |  |  | Time of CMIN Observation | TMIN (h) | 0 |
|  |  |  | Min Conc | CMIN (ug/L) | 9.4149 |
|  |  |  | Min Conc Norm by Dose | CMIND (ug/L/mg) | 0.94149 |
|  |  |  | Time of Last Nonzero Conc | TLST (h) | 72 |
|  |  |  | Last Nonzero Conc | CLST (ug/L) | 2.9773 |
|  |  |  | Last Nonzero Conc Pred | CLSTP (ug/L) | 2.74269 |
|  |  |  | Average Concentration | CAVG (ug/L) | 51.9256 |
|  |  |  | Conc Trough | CTAU (ug/L) | 12.1909 |
|  |  |  | AUC All | AUCALL (ug/L\*h) | 1525.66 |
|  |  |  | AUC Infinity Obs | AUCIFO (ug/L\*h) | 1627.04 |
|  |  |  | AUC Infinity Obs Norm by Dose | AUCIFOD (ug/L\*h/mg) | 162.704 |
|  |  |  | AUC Infinity Pred | AUCIFP (ug/L\*h) | 1619.05 |
|  |  |  | AUC Infinity Pred Norm by Dose | AUCIFPD (ug/L\*h/mg) | 161.905 |
|  |  |  | AUC to Last Nonzero Conc | AUCLST (ug/L\*h) | 1525.66 |
|  |  |  | AUC to Last Nonzero Conc Norm by Dose | AUCLSTD (ug/L\*h/mg) | 152.566 |
|  |  |  | AUC %Extrapolation Obs | AUCPEO (%) | 6.23085 |
|  |  |  | AUC %Extrapolation Pred | AUCPEP (%) | 5.76819 |
|  |  |  | AUC Over Dosing Interval | AUCTAU (ug/L\*h) | 1246.21 |
|  |  |  | AUC Over Dosing Interval Norm by Dose | AUCTAUD (ug/L\*h/mg) | 124.621 |
|  |  |  | Total CL by F for Dose Int | CLFSS (L/h) | 8.0243 |
|  |  |  | Vz for Dose Int at SS by F | VZFSS (L) | 273.231 |

NC: Not calculated.
Number of significant digits: 6
IQnca version: 1.3.1.9000
Script: compliance
Output: output/listings/01\_listings\_NCA.rmd
Execution date: 2023-12-04 14:26:26.27011

**Individual pharmacokinetic parameters of Plasma C (C)**

* USUBJID: 5

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Profile | Group | Dose [mg] | Description | Parameter (Unit) | Value |
| First dose | 10mg\_OD\_Oral | 10 | Number of Points for Lambda z | LAMZNPT (-) | 5 |
|  |  |  | R Squared Adjusted | R2ADJ (-) | 0.989982 |
|  |  |  | Half-Life Lambda z | LAMZHL (h) | 5.82835 |
|  |  |  | Span | SPAN (-) | 3.4315 |
|  |  |  | Time Until First Nonzero Conc | TLAG (h) | 0 |
|  |  |  | Time of CMAX | TMAX (h) | 2 |
|  |  |  | Max Conc | CMAX (ug/L) | 107.757 |
|  |  |  | Max Conc Norm by Dose | CMAXD (ug/L/mg) | 10.7757 |
|  |  |  | Time of CMIN Observation | TMIN (h) | 0 |
|  |  |  | Min Conc | CMIN (ug/L) | 0 |
|  |  |  | Min Conc Norm by Dose | CMIND (ug/L/mg) | 0 |
|  |  |  | Time of Last Nonzero Conc | TLST (h) | 24 |
|  |  |  | Last Nonzero Conc | CLST (ug/L) | 9.2714 |
|  |  |  | Last Nonzero Conc Pred | CLSTP (ug/L) | 8.78888 |
|  |  |  | Average Concentration | CAVG (ug/L) | 43.9375 |
|  |  |  | Conc Trough | CTAU (ug/L) | 9.2714 |
|  |  |  | AUC All | AUCALL (ug/L\*h) | 1054.5 |
|  |  |  | AUC Infinity Obs | AUCIFO (ug/L\*h) | 1132.46 |
|  |  |  | AUC Infinity Obs Norm by Dose | AUCIFOD (ug/L\*h/mg) | 113.246 |
|  |  |  | AUC Infinity Pred | AUCIFP (ug/L\*h) | 1128.4 |
|  |  |  | AUC Infinity Pred Norm by Dose | AUCIFPD (ug/L\*h/mg) | 112.84 |
|  |  |  | AUC to Last Nonzero Conc | AUCLST (ug/L\*h) | 1054.5 |
|  |  |  | AUC to Last Nonzero Conc Norm by Dose | AUCLSTD (ug/L\*h/mg) | 105.45 |
|  |  |  | AUC %Extrapolation Obs | AUCPEO (%) | 6.88403 |
|  |  |  | AUC %Extrapolation Pred | AUCPEP (%) | 6.54922 |
|  |  |  | AUC Over Dosing Interval | AUCTAU (ug/L\*h) | 1054.5 |
|  |  |  | AUC Over Dosing Interval Norm by Dose | AUCTAUD (ug/L\*h/mg) | 105.45 |
|  |  |  | Total CL Obs by F | CLFO (L/h) | 8.83035 |
|  |  |  | Total CL Pred by F | CLFP (L/h) | 8.8621 |
|  |  |  | Vz Obs by F | VZFO (L) | 74.2502 |
|  |  |  | Vz Pred by F | VZFP (L) | 74.5172 |

NC: Not calculated.
Number of significant digits: 6
IQnca version: 1.3.1.9000
Script: compliance
Output: output/listings/01\_listings\_NCA.rmd
Execution date: 2023-12-04 14:26:26.280699

**Individual pharmacokinetic parameters of Plasma C (C)**

* USUBJID: 5

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Profile | Group | Dose [mg] | Description | Parameter (Unit) | Value |
| Steady-state dose | 10mg\_OD\_Oral | 10 | Number of Points for Lambda z | LAMZNPT (-) | 4 |
|  |  |  | R Squared Adjusted | R2ADJ (-) | 0.934595 |
|  |  |  | Half-Life Lambda z | LAMZHL (h) | 22.0356 |
|  |  |  | Span | SPAN (-) | 2.54134 |
|  |  |  | Time Until First Nonzero Conc | TLAG (h) | 0 |
|  |  |  | Time of CMAX | TMAX (h) | 4 |
|  |  |  | Max Conc | CMAX (ug/L) | 109.515 |
|  |  |  | Max Conc Norm by Dose | CMAXD (ug/L/mg) | 10.9515 |
|  |  |  | Time of CMIN Observation | TMIN (h) | 0 |
|  |  |  | Min Conc | CMIN (ug/L) | 15.2841 |
|  |  |  | Min Conc Norm by Dose | CMIND (ug/L/mg) | 1.52841 |
|  |  |  | Time of Last Nonzero Conc | TLST (h) | 72 |
|  |  |  | Last Nonzero Conc | CLST (ug/L) | 5.4618 |
|  |  |  | Last Nonzero Conc Pred | CLSTP (ug/L) | 4.76789 |
|  |  |  | Average Concentration | CAVG (ug/L) | 58.1818 |
|  |  |  | Conc Trough | CTAU (ug/L) | 21.1754 |
|  |  |  | AUC All | AUCALL (ug/L\*h) | 1881.79 |
|  |  |  | AUC Infinity Obs | AUCIFO (ug/L\*h) | 2055.42 |
|  |  |  | AUC Infinity Obs Norm by Dose | AUCIFOD (ug/L\*h/mg) | 205.542 |
|  |  |  | AUC Infinity Pred | AUCIFP (ug/L\*h) | 2033.36 |
|  |  |  | AUC Infinity Pred Norm by Dose | AUCIFPD (ug/L\*h/mg) | 203.336 |
|  |  |  | AUC to Last Nonzero Conc | AUCLST (ug/L\*h) | 1881.79 |
|  |  |  | AUC to Last Nonzero Conc Norm by Dose | AUCLSTD (ug/L\*h/mg) | 188.179 |
|  |  |  | AUC %Extrapolation Obs | AUCPEO (%) | 8.44762 |
|  |  |  | AUC %Extrapolation Pred | AUCPEP (%) | 7.45437 |
|  |  |  | AUC Over Dosing Interval | AUCTAU (ug/L\*h) | 1396.36 |
|  |  |  | AUC Over Dosing Interval Norm by Dose | AUCTAUD (ug/L\*h/mg) | 139.636 |
|  |  |  | Total CL by F for Dose Int | CLFSS (L/h) | 7.16145 |
|  |  |  | Vz for Dose Int at SS by F | VZFSS (L) | 227.668 |

NC: Not calculated.
Number of significant digits: 6
IQnca version: 1.3.1.9000
Script: compliance
Output: output/listings/01\_listings\_NCA.rmd
Execution date: 2023-12-04 14:26:26.29065

**Individual pharmacokinetic parameters of Plasma C (C)**

* USUBJID: 6

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Profile | Group | Dose [mg] | Description | Parameter (Unit) | Value |
| First dose | 10mg\_OD\_Oral | 10 | Number of Points for Lambda z | LAMZNPT (-) | 3 |
|  |  |  | R Squared Adjusted | R2ADJ (-) | 0.997024 |
|  |  |  | Half-Life Lambda z | LAMZHL (h) | 7.20302 |
|  |  |  | Span | SPAN (-) | 1.66597 |
|  |  |  | Time Until First Nonzero Conc | TLAG (h) | 0 |
|  |  |  | Time of CMAX | TMAX (h) | 2 |
|  |  |  | Max Conc | CMAX (ug/L) | 138.268 |
|  |  |  | Max Conc Norm by Dose | CMAXD (ug/L/mg) | 13.8268 |
|  |  |  | Time of CMIN Observation | TMIN (h) | 0 |
|  |  |  | Min Conc | CMIN (ug/L) | 0 |
|  |  |  | Min Conc Norm by Dose | CMIND (ug/L/mg) | 0 |
|  |  |  | Time of Last Nonzero Conc | TLST (h) | 24 |
|  |  |  | Last Nonzero Conc | CLST (ug/L) | 18.6904 |
|  |  |  | Last Nonzero Conc Pred | CLSTP (ug/L) | 18.5307 |
|  |  |  | Average Concentration | CAVG (ug/L) | 66.966 |
|  |  |  | Conc Trough | CTAU (ug/L) | 18.6904 |
|  |  |  | AUC All | AUCALL (ug/L\*h) | 1607.18 |
|  |  |  | AUC Infinity Obs | AUCIFO (ug/L\*h) | 1801.41 |
|  |  |  | AUC Infinity Obs Norm by Dose | AUCIFOD (ug/L\*h/mg) | 180.141 |
|  |  |  | AUC Infinity Pred | AUCIFP (ug/L\*h) | 1799.75 |
|  |  |  | AUC Infinity Pred Norm by Dose | AUCIFPD (ug/L\*h/mg) | 179.975 |
|  |  |  | AUC to Last Nonzero Conc | AUCLST (ug/L\*h) | 1607.18 |
|  |  |  | AUC to Last Nonzero Conc Norm by Dose | AUCLSTD (ug/L\*h/mg) | 160.718 |
|  |  |  | AUC %Extrapolation Obs | AUCPEO (%) | 10.7819 |
|  |  |  | AUC %Extrapolation Pred | AUCPEP (%) | 10.6996 |
|  |  |  | AUC Over Dosing Interval | AUCTAU (ug/L\*h) | 1607.18 |
|  |  |  | AUC Over Dosing Interval Norm by Dose | AUCTAUD (ug/L\*h/mg) | 160.718 |
|  |  |  | Total CL Obs by F | CLFO (L/h) | 5.55121 |
|  |  |  | Total CL Pred by F | CLFP (L/h) | 5.55632 |
|  |  |  | Vz Obs by F | VZFO (L) | 57.6868 |
|  |  |  | Vz Pred by F | VZFP (L) | 57.74 |

NC: Not calculated.
Number of significant digits: 6
IQnca version: 1.3.1.9000
Script: compliance
Output: output/listings/01\_listings\_NCA.rmd
Execution date: 2023-12-04 14:26:26.30076

**Individual pharmacokinetic parameters of Plasma C (C)**

* USUBJID: 6

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Profile | Group | Dose [mg] | Description | Parameter (Unit) | Value |
| Steady-state dose | 10mg\_OD\_Oral | 10 | Number of Points for Lambda z | LAMZNPT (-) | 3 |
|  |  |  | R Squared Adjusted | R2ADJ (-) | 0.996472 |
|  |  |  | Half-Life Lambda z | LAMZHL (h) | 35.7289 |
|  |  |  | Span | SPAN (-) | 3.35862 |
|  |  |  | Time Until First Nonzero Conc | TLAG (h) | 0 |
|  |  |  | Time of CMAX | TMAX (h) | 2 |
|  |  |  | Max Conc | CMAX (ug/L) | 179.491 |
|  |  |  | Max Conc Norm by Dose | CMAXD (ug/L/mg) | 17.9491 |
|  |  |  | Time of CMIN Observation | TMIN (h) | 24 |
|  |  |  | Min Conc | CMIN (ug/L) | 32.6835 |
|  |  |  | Min Conc Norm by Dose | CMIND (ug/L/mg) | 3.26835 |
|  |  |  | Time of Last Nonzero Conc | TLST (h) | 168 |
|  |  |  | Last Nonzero Conc | CLST (ug/L) | 1.5565 |
|  |  |  | Last Nonzero Conc Pred | CLSTP (ug/L) | 1.57419 |
|  |  |  | Average Concentration | CAVG (ug/L) | 95.5816 |
|  |  |  | Conc Trough | CTAU (ug/L) | 32.6835 |
|  |  |  | AUC All | AUCALL (ug/L\*h) | 3612.26 |
|  |  |  | AUC Infinity Obs | AUCIFO (ug/L\*h) | 3692.49 |
|  |  |  | AUC Infinity Obs Norm by Dose | AUCIFOD (ug/L\*h/mg) | 369.249 |
|  |  |  | AUC Infinity Pred | AUCIFP (ug/L\*h) | 3693.4 |
|  |  |  | AUC Infinity Pred Norm by Dose | AUCIFPD (ug/L\*h/mg) | 369.34 |
|  |  |  | AUC to Last Nonzero Conc | AUCLST (ug/L\*h) | 3612.26 |
|  |  |  | AUC to Last Nonzero Conc Norm by Dose | AUCLSTD (ug/L\*h/mg) | 361.226 |
|  |  |  | AUC %Extrapolation Obs | AUCPEO (%) | 2.17282 |
|  |  |  | AUC %Extrapolation Pred | AUCPEP (%) | 2.19697 |
|  |  |  | AUC Over Dosing Interval | AUCTAU (ug/L\*h) | 2293.96 |
|  |  |  | AUC Over Dosing Interval Norm by Dose | AUCTAUD (ug/L\*h/mg) | 229.396 |
|  |  |  | Total CL by F for Dose Int | CLFSS (L/h) | 4.35927 |
|  |  |  | Vz for Dose Int at SS by F | VZFSS (L) | 224.703 |

NC: Not calculated.
Number of significant digits: 6
IQnca version: 1.3.1.9000
Script: compliance
Output: output/listings/01\_listings\_NCA.rmd
Execution date: 2023-12-04 14:26:26.310731

**Individual pharmacokinetic parameters of Plasma C (C)**

* USUBJID: 7

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Profile | Group | Dose [mg] | Description | Parameter (Unit) | Value |
| First dose | 10mg\_OD\_Oral | 10 | Number of Points for Lambda z | LAMZNPT (-) | 4 |
|  |  |  | R Squared Adjusted | R2ADJ (-) | 0.975561 |
|  |  |  | Half-Life Lambda z | LAMZHL (h) | 5.90162 |
|  |  |  | Span | SPAN (-) | 2.71112 |
|  |  |  | Time Until First Nonzero Conc | TLAG (h) | 0 |
|  |  |  | Time of CMAX | TMAX (h) | 4 |
|  |  |  | Max Conc | CMAX (ug/L) | 126.461 |
|  |  |  | Max Conc Norm by Dose | CMAXD (ug/L/mg) | 12.6461 |
|  |  |  | Time of CMIN Observation | TMIN (h) | 0 |
|  |  |  | Min Conc | CMIN (ug/L) | 0 |
|  |  |  | Min Conc Norm by Dose | CMIND (ug/L/mg) | 0 |
|  |  |  | Time of Last Nonzero Conc | TLST (h) | 24 |
|  |  |  | Last Nonzero Conc | CLST (ug/L) | 15.8944 |
|  |  |  | Last Nonzero Conc Pred | CLSTP (ug/L) | 15.029 |
|  |  |  | Average Concentration | CAVG (ug/L) | 64.3178 |
|  |  |  | Conc Trough | CTAU (ug/L) | 15.8944 |
|  |  |  | AUC All | AUCALL (ug/L\*h) | 1543.63 |
|  |  |  | AUC Infinity Obs | AUCIFO (ug/L\*h) | 1678.96 |
|  |  |  | AUC Infinity Obs Norm by Dose | AUCIFOD (ug/L\*h/mg) | 167.896 |
|  |  |  | AUC Infinity Pred | AUCIFP (ug/L\*h) | 1671.59 |
|  |  |  | AUC Infinity Pred Norm by Dose | AUCIFPD (ug/L\*h/mg) | 167.159 |
|  |  |  | AUC to Last Nonzero Conc | AUCLST (ug/L\*h) | 1543.63 |
|  |  |  | AUC to Last Nonzero Conc Norm by Dose | AUCLSTD (ug/L\*h/mg) | 154.363 |
|  |  |  | AUC %Extrapolation Obs | AUCPEO (%) | 8.06028 |
|  |  |  | AUC %Extrapolation Pred | AUCPEP (%) | 7.65504 |
|  |  |  | AUC Over Dosing Interval | AUCTAU (ug/L\*h) | 1543.63 |
|  |  |  | AUC Over Dosing Interval Norm by Dose | AUCTAUD (ug/L\*h/mg) | 154.363 |
|  |  |  | Total CL Obs by F | CLFO (L/h) | 5.95608 |
|  |  |  | Total CL Pred by F | CLFP (L/h) | 5.98233 |
|  |  |  | Vz Obs by F | VZFO (L) | 50.7115 |
|  |  |  | Vz Pred by F | VZFP (L) | 50.935 |

NC: Not calculated.
Number of significant digits: 6
IQnca version: 1.3.1.9000
Script: compliance
Output: output/listings/01\_listings\_NCA.rmd
Execution date: 2023-12-04 14:26:26.320379

**Individual pharmacokinetic parameters of Plasma C (C)**

* USUBJID: 7

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Profile | Group | Dose [mg] | Description | Parameter (Unit) | Value |
| Steady-state dose | 10mg\_OD\_Oral | 10 | Number of Points for Lambda z | LAMZNPT (-) | 3 |
|  |  |  | R Squared Adjusted | R2ADJ (-) | 0.998739 |
|  |  |  | Half-Life Lambda z | LAMZHL (h) | 74.5993 |
|  |  |  | Span | SPAN (-) | 1.60859 |
|  |  |  | Time Until First Nonzero Conc | TLAG (h) | 0 |
|  |  |  | Time of CMAX | TMAX (h) | 2 |
|  |  |  | Max Conc | CMAX (ug/L) | 155.549 |
|  |  |  | Max Conc Norm by Dose | CMAXD (ug/L/mg) | 15.5549 |
|  |  |  | Time of CMIN Observation | TMIN (h) | 0 |
|  |  |  | Min Conc | CMIN (ug/L) | 19.7266 |
|  |  |  | Min Conc Norm by Dose | CMIND (ug/L/mg) | 1.97266 |
|  |  |  | Time of Last Nonzero Conc | TLST (h) | 168 |
|  |  |  | Last Nonzero Conc | CLST (ug/L) | 3.218 |
|  |  |  | Last Nonzero Conc Pred | CLSTP (ug/L) | 3.20761 |
|  |  |  | Average Concentration | CAVG (ug/L) | 79.956 |
|  |  |  | Conc Trough | CTAU (ug/L) | 25.3684 |
|  |  |  | AUC All | AUCALL (ug/L\*h) | 3017.05 |
|  |  |  | AUC Infinity Obs | AUCIFO (ug/L\*h) | 3363.38 |
|  |  |  | AUC Infinity Obs Norm by Dose | AUCIFOD (ug/L\*h/mg) | 336.338 |
|  |  |  | AUC Infinity Pred | AUCIFP (ug/L\*h) | 3362.26 |
|  |  |  | AUC Infinity Pred Norm by Dose | AUCIFPD (ug/L\*h/mg) | 336.226 |
|  |  |  | AUC to Last Nonzero Conc | AUCLST (ug/L\*h) | 3017.05 |
|  |  |  | AUC to Last Nonzero Conc Norm by Dose | AUCLSTD (ug/L\*h/mg) | 301.705 |
|  |  |  | AUC %Extrapolation Obs | AUCPEO (%) | 10.2972 |
|  |  |  | AUC %Extrapolation Pred | AUCPEP (%) | 10.2674 |
|  |  |  | AUC Over Dosing Interval | AUCTAU (ug/L\*h) | 1918.95 |
|  |  |  | AUC Over Dosing Interval Norm by Dose | AUCTAUD (ug/L\*h/mg) | 191.895 |
|  |  |  | Total CL by F for Dose Int | CLFSS (L/h) | 5.2112 |
|  |  |  | Vz for Dose Int at SS by F | VZFSS (L) | 560.85 |

NC: Not calculated.
Number of significant digits: 6
IQnca version: 1.3.1.9000
Script: compliance
Output: output/listings/01\_listings\_NCA.rmd
Execution date: 2023-12-04 14:26:26.329897

**Individual pharmacokinetic parameters of Plasma C (C)**

* USUBJID: 8

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Profile | Group | Dose [mg] | Description | Parameter (Unit) | Value |
| First dose | 10mg\_OD\_Oral | 10 | Number of Points for Lambda z | LAMZNPT (-) | 4 |
|  |  |  | R Squared Adjusted | R2ADJ (-) | 0.972306 |
|  |  |  | Half-Life Lambda z | LAMZHL (h) | 8.53988 |
|  |  |  | Span | SPAN (-) | 1.87356 |
|  |  |  | Time Until First Nonzero Conc | TLAG (h) | 0 |
|  |  |  | Time of CMAX | TMAX (h) | 2 |
|  |  |  | Max Conc | CMAX (ug/L) | 87.0207 |
|  |  |  | Max Conc Norm by Dose | CMAXD (ug/L/mg) | 8.70207 |
|  |  |  | Time of CMIN Observation | TMIN (h) | 0 |
|  |  |  | Min Conc | CMIN (ug/L) | 0 |
|  |  |  | Min Conc Norm by Dose | CMIND (ug/L/mg) | 0 |
|  |  |  | Time of Last Nonzero Conc | TLST (h) | 24 |
|  |  |  | Last Nonzero Conc | CLST (ug/L) | 22.8675 |
|  |  |  | Last Nonzero Conc Pred | CLSTP (ug/L) | 21.7793 |
|  |  |  | Average Concentration | CAVG (ug/L) | 54.318 |
|  |  |  | Conc Trough | CTAU (ug/L) | 22.8675 |
|  |  |  | AUC All | AUCALL (ug/L\*h) | 1303.63 |
|  |  |  | AUC Infinity Obs | AUCIFO (ug/L\*h) | 1585.37 |
|  |  |  | AUC Infinity Obs Norm by Dose | AUCIFOD (ug/L\*h/mg) | 158.537 |
|  |  |  | AUC Infinity Pred | AUCIFP (ug/L\*h) | 1571.96 |
|  |  |  | AUC Infinity Pred Norm by Dose | AUCIFPD (ug/L\*h/mg) | 157.196 |
|  |  |  | AUC to Last Nonzero Conc | AUCLST (ug/L\*h) | 1303.63 |
|  |  |  | AUC to Last Nonzero Conc Norm by Dose | AUCLSTD (ug/L\*h/mg) | 130.363 |
|  |  |  | AUC %Extrapolation Obs | AUCPEO (%) | 17.7711 |
|  |  |  | AUC %Extrapolation Pred | AUCPEP (%) | 17.0698 |
|  |  |  | AUC Over Dosing Interval | AUCTAU (ug/L\*h) | 1303.63 |
|  |  |  | AUC Over Dosing Interval Norm by Dose | AUCTAUD (ug/L\*h/mg) | 130.363 |
|  |  |  | Total CL Obs by F | CLFO (L/h) | 6.30768 |
|  |  |  | Total CL Pred by F | CLFP (L/h) | 6.36148 |
|  |  |  | Vz Obs by F | VZFO (L) | 77.7134 |
|  |  |  | Vz Pred by F | VZFP (L) | 78.3762 |

NC: Not calculated.
Number of significant digits: 6
IQnca version: 1.3.1.9000
Script: compliance
Output: output/listings/01\_listings\_NCA.rmd
Execution date: 2023-12-04 14:26:26.343263

**Individual pharmacokinetic parameters of Plasma C (C)**

* USUBJID: 8

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Profile | Group | Dose [mg] | Description | Parameter (Unit) | Value |
| Steady-state dose | 10mg\_OD\_Oral | 10 | Number of Points for Lambda z | LAMZNPT (-) | 3 |
|  |  |  | R Squared Adjusted | R2ADJ (-) | 0.99974 |
|  |  |  | Half-Life Lambda z | LAMZHL (h) | 51.5814 |
|  |  |  | Span | SPAN (-) | 2.32642 |
|  |  |  | Time Until First Nonzero Conc | TLAG (h) | 0 |
|  |  |  | Time of CMAX | TMAX (h) | 4 |
|  |  |  | Max Conc | CMAX (ug/L) | 126.63 |
|  |  |  | Max Conc Norm by Dose | CMAXD (ug/L/mg) | 12.663 |
|  |  |  | Time of CMIN Observation | TMIN (h) | 24 |
|  |  |  | Min Conc | CMIN (ug/L) | 37.1 |
|  |  |  | Min Conc Norm by Dose | CMIND (ug/L/mg) | 3.71 |
|  |  |  | Time of Last Nonzero Conc | TLST (h) | 168 |
|  |  |  | Last Nonzero Conc | CLST (ug/L) | 3.4493 |
|  |  |  | Last Nonzero Conc Pred | CLSTP (ug/L) | 3.44198 |
|  |  |  | Average Concentration | CAVG (ug/L) | 81.1561 |
|  |  |  | Conc Trough | CTAU (ug/L) | 37.1 |
|  |  |  | AUC All | AUCALL (ug/L\*h) | 3596.98 |
|  |  |  | AUC Infinity Obs | AUCIFO (ug/L\*h) | 3853.66 |
|  |  |  | AUC Infinity Obs Norm by Dose | AUCIFOD (ug/L\*h/mg) | 385.366 |
|  |  |  | AUC Infinity Pred | AUCIFP (ug/L\*h) | 3853.12 |
|  |  |  | AUC Infinity Pred Norm by Dose | AUCIFPD (ug/L\*h/mg) | 385.312 |
|  |  |  | AUC to Last Nonzero Conc | AUCLST (ug/L\*h) | 3596.98 |
|  |  |  | AUC to Last Nonzero Conc Norm by Dose | AUCLSTD (ug/L\*h/mg) | 359.698 |
|  |  |  | AUC %Extrapolation Obs | AUCPEO (%) | 6.66077 |
|  |  |  | AUC %Extrapolation Pred | AUCPEP (%) | 6.64758 |
|  |  |  | AUC Over Dosing Interval | AUCTAU (ug/L\*h) | 1947.75 |
|  |  |  | AUC Over Dosing Interval Norm by Dose | AUCTAUD (ug/L\*h/mg) | 194.775 |
|  |  |  | Total CL by F for Dose Int | CLFSS (L/h) | 5.13414 |
|  |  |  | Vz for Dose Int at SS by F | VZFSS (L) | 382.063 |

NC: Not calculated.
Number of significant digits: 6
IQnca version: 1.3.1.9000
Script: compliance
Output: output/listings/01\_listings\_NCA.rmd
Execution date: 2023-12-04 14:26:26.355377

**Individual pharmacokinetic parameters of Plasma C (C)**

* USUBJID: 9

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Profile | Group | Dose [mg] | Description | Parameter (Unit) | Value |
| First dose | 10mg\_OD\_Oral | 10 | Number of Points for Lambda z | LAMZNPT (-) | 4 |
|  |  |  | R Squared Adjusted | R2ADJ (-) | 0.988142 |
|  |  |  | Half-Life Lambda z | LAMZHL (h) | 8.27585 |
|  |  |  | Span | SPAN (-) | 1.93334 |
|  |  |  | Time Until First Nonzero Conc | TLAG (h) | 0 |
|  |  |  | Time of CMAX | TMAX (h) | 4 |
|  |  |  | Max Conc | CMAX (ug/L) | 96.12 |
|  |  |  | Max Conc Norm by Dose | CMAXD (ug/L/mg) | 9.612 |
|  |  |  | Time of CMIN Observation | TMIN (h) | 0 |
|  |  |  | Min Conc | CMIN (ug/L) | 0 |
|  |  |  | Min Conc Norm by Dose | CMIND (ug/L/mg) | 0 |
|  |  |  | Time of Last Nonzero Conc | TLST (h) | 24 |
|  |  |  | Last Nonzero Conc | CLST (ug/L) | 19.3411 |
|  |  |  | Last Nonzero Conc Pred | CLSTP (ug/L) | 20.062 |
|  |  |  | Average Concentration | CAVG (ug/L) | 55.4499 |
|  |  |  | Conc Trough | CTAU (ug/L) | 19.3411 |
|  |  |  | AUC All | AUCALL (ug/L\*h) | 1330.8 |
|  |  |  | AUC Infinity Obs | AUCIFO (ug/L\*h) | 1561.72 |
|  |  |  | AUC Infinity Obs Norm by Dose | AUCIFOD (ug/L\*h/mg) | 156.172 |
|  |  |  | AUC Infinity Pred | AUCIFP (ug/L\*h) | 1570.33 |
|  |  |  | AUC Infinity Pred Norm by Dose | AUCIFPD (ug/L\*h/mg) | 157.033 |
|  |  |  | AUC to Last Nonzero Conc | AUCLST (ug/L\*h) | 1330.8 |
|  |  |  | AUC to Last Nonzero Conc Norm by Dose | AUCLSTD (ug/L\*h/mg) | 133.08 |
|  |  |  | AUC %Extrapolation Obs | AUCPEO (%) | 14.7865 |
|  |  |  | AUC %Extrapolation Pred | AUCPEP (%) | 15.2535 |
|  |  |  | AUC Over Dosing Interval | AUCTAU (ug/L\*h) | 1330.8 |
|  |  |  | AUC Over Dosing Interval Norm by Dose | AUCTAUD (ug/L\*h/mg) | 133.08 |
|  |  |  | Total CL Obs by F | CLFO (L/h) | 6.40319 |
|  |  |  | Total CL Pred by F | CLFP (L/h) | 6.3681 |
|  |  |  | Vz Obs by F | VZFO (L) | 76.4511 |
|  |  |  | Vz Pred by F | VZFP (L) | 76.0321 |

NC: Not calculated.
Number of significant digits: 6
IQnca version: 1.3.1.9000
Script: compliance
Output: output/listings/01\_listings\_NCA.rmd
Execution date: 2023-12-04 14:26:26.364463

**Individual pharmacokinetic parameters of Plasma C (C)**

* USUBJID: 9

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Profile | Group | Dose [mg] | Description | Parameter (Unit) | Value |
| Steady-state dose | 10mg\_OD\_Oral | 10 | Number of Points for Lambda z | LAMZNPT (-) | 3 |
|  |  |  | R Squared Adjusted | R2ADJ (-) | 0.986624 |
|  |  |  | Half-Life Lambda z | LAMZHL (h) | 48.9217 |
|  |  |  | Span | SPAN (-) | 2.4529 |
|  |  |  | Time Until First Nonzero Conc | TLAG (h) | 0 |
|  |  |  | Time of CMAX | TMAX (h) | 4 |
|  |  |  | Max Conc | CMAX (ug/L) | 121.854 |
|  |  |  | Max Conc Norm by Dose | CMAXD (ug/L/mg) | 12.1854 |
|  |  |  | Time of CMIN Observation | TMIN (h) | 24 |
|  |  |  | Min Conc | CMIN (ug/L) | 33.1237 |
|  |  |  | Min Conc Norm by Dose | CMIND (ug/L/mg) | 3.31237 |
|  |  |  | Time of Last Nonzero Conc | TLST (h) | 168 |
|  |  |  | Last Nonzero Conc | CLST (ug/L) | 2.4386 |
|  |  |  | Last Nonzero Conc Pred | CLSTP (ug/L) | 2.39963 |
|  |  |  | Average Concentration | CAVG (ug/L) | 77.8631 |
|  |  |  | Conc Trough | CTAU (ug/L) | 33.1237 |
|  |  |  | AUC All | AUCALL (ug/L\*h) | 3138.56 |
|  |  |  | AUC Infinity Obs | AUCIFO (ug/L\*h) | 3310.68 |
|  |  |  | AUC Infinity Obs Norm by Dose | AUCIFOD (ug/L\*h/mg) | 331.068 |
|  |  |  | AUC Infinity Pred | AUCIFP (ug/L\*h) | 3307.93 |
|  |  |  | AUC Infinity Pred Norm by Dose | AUCIFPD (ug/L\*h/mg) | 330.793 |
|  |  |  | AUC to Last Nonzero Conc | AUCLST (ug/L\*h) | 3138.56 |
|  |  |  | AUC to Last Nonzero Conc Norm by Dose | AUCLSTD (ug/L\*h/mg) | 313.856 |
|  |  |  | AUC %Extrapolation Obs | AUCPEO (%) | 5.19876 |
|  |  |  | AUC %Extrapolation Pred | AUCPEP (%) | 5.11994 |
|  |  |  | AUC Over Dosing Interval | AUCTAU (ug/L\*h) | 1868.71 |
|  |  |  | AUC Over Dosing Interval Norm by Dose | AUCTAUD (ug/L\*h/mg) | 186.871 |
|  |  |  | Total CL by F for Dose Int | CLFSS (L/h) | 5.35127 |
|  |  |  | Vz for Dose Int at SS by F | VZFSS (L) | 377.688 |

NC: Not calculated.
Number of significant digits: 6
IQnca version: 1.3.1.9000
Script: compliance
Output: output/listings/01\_listings\_NCA.rmd
Execution date: 2023-12-04 14:26:26.374017